

AMENDMENTS TO THE CLAIMS

1-32. (Canceled)

33. (Previously presented) A method according to claim 34, wherein said device is wholly implanted subcutaneously in said host.

34. (Previously presented) A method of measuring glucose in a biological fluid, comprising the steps of:

- a) providing a host;
- b) providing an implantable device comprising a sensor capable of continuous glucose sensing, said sensor having a protruding interface tip, said implantable device comprising a housing, a sensing membrane, a first domain, and a second domain; wherein said first domain is positioned more distal to said housing than said second domain; wherein said first domain supports tissue ingrowth; wherein said sensing membrane is positioned more proximal to said housing than said second domain; wherein said sensing membrane comprises an enzyme; wherein said second domain is situated between said first domain and said sensing membrane; wherein said first domain is disposed on at least a portion of said interface tip; and wherein said second domain is impermeable to macrophages;
- c) implanting said device subcutaneously into tissue of said host so as to elicit a foreign body capsule as a result of the response of said host to the introduction of said implantable device, said sensor interface tip communicating with the tissue of said host such that said tip is anchored by tissue ingrowth in said foreign body capsule.

35. (Previously presented) A method according to claim 34, wherein said second domain comprises an angiogenic layer.

36-37. (Canceled)

38. (Previously presented) A method of monitoring glucose levels, comprising:

- a) providing i) a host, and ii) a device comprising a housing and a sensor capable of continuous glucose sensing, said sensor comprising a sensor interface tip comprising a sensing membrane, a first domain, and a second domain; wherein said device comprises a body and wherein said sensor interface tip protrudes beyond a plane of the body to assist in formation of vasculature; wherein said first domain is positioned more distal to said housing than said second domain; wherein said first domain supports tissue ingrowth; wherein said sensing membrane is

positioned more proximal to said housing than said second domain; wherein said sensing membrane comprising an enzyme; wherein said second domain is situated between said first domain and said sensing membrane; and wherein said second domain is impermeable to macrophages; and

b) wholly implanting said device subcutaneously in said host under conditions such that said device provides continuous glucose sensing, wherein said device is anchored in said host by tissue ingrowth.

39. (Previously presented) A method according to claim 38, wherein said second domain is a vascularization promotion layer.

40. (Canceled)

41. (Previously presented) A method according to claim 38, wherein said implant is sized and configured for being wholly implanted subcutaneously.

42. (Previously presented) A method according to claim 41, further including the step of transmitting data from said wholly implanted device telemetrically.

43-47. (Canceled)

48. (Previously presented) The method of claim 34, wherein said enzyme comprises glucose oxidase.

49. (Previously presented) The method of claim 38, wherein said enzyme comprises glucose oxidase.

50-53. (Canceled)

54. (Previously presented) The method of claim 34, wherein said implantable device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.

55. (Previously presented) The method of claim 38, wherein said device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.

56. (Previously presented) The method of claim 38, further comprising implanting said device in said host under conditions such that said device measures said glucose accurately for a period of time exceeding 90 days.

57. (Previously presented) The method of claim 56, wherein said device measures said glucose accurately for a period exceeding 150 days.

58. (Previously presented) The method of claim 56, wherein said device measures said glucose accurately for a period exceeding 360 days.

59. (Previously presented) The method of claim 38, further comprising explanting said device after 90 days.

60. (Previously presented) The method of claim 59, wherein said device is explanted after 150 days.

61. (Previously presented) The method of claim 59, wherein said device is explanted after 360 days.

62. (Previously presented) The method of claim 38, wherein said first domain stabilizes over a time period to produce long-term level reflecting adequate microcirculatory delivery of glucose and oxygen to said sensor.

63. (Previously presented) The method of claim 38, wherein said first domain is formed from a material selected from the group consisting of polytetrafluoroethylene, hydrophilic polyvinylidene fluoride, mixed cellulose esters, polyvinyl chloride, polyethylene, polypropylene, Teflon, cellulose acetate, cellulose nitrate, polycarbonate, polyester, nylon, polysulphone, polymethacrylate, mixed esters of cellulose polyvinylidene difluoride, silicone, and polyacrylonitrile.

64. (Previously presented) The method of claim 38, wherein said vascular promotion layer comprises a material that has a characteristic of stimulating growth of new vascular structures by said host close to said device.

65. (Previously presented) The method of claim 38, wherein said sensor senses glucose using an enzymatic mechanism.

66. (Previously presented) The method of claim 38, wherein said sensor senses glucose using a non-enzymatic mechanism.

67. (Previously presented) The method of claim 38, wherein said sensor senses glucose using a resonance mechanism.

68. (Previously presented) The method of claim 38, wherein said sensor senses glucose using an acoustic wave mechanism.

69. (Previously presented) The method of claim 38, wherein said sensor senses glucose using an optical mechanism.

70. (Previously presented) The method of claim 34, further comprising implanting said device in said host under conditions such that said device measures said glucose accurately for a period of time exceeding 90 days.

71. (Previously presented) The method of claim 70, wherein said device measures said glucose accurately for a period exceeding 150 days.

72. (Previously presented) The method of claim 70, wherein said device measures said glucose accurately for a period exceeding 360 days.

73. (Previously presented) The method of claim 34, further comprising explanting said device after 90 days.

74. (Previously presented) The method of claim 73, wherein said device is explanted after 150 days.

75. (Previously presented) The method of claim 73, wherein said device is explanted after 360 days.

76. (Previously presented) The method of claim 34, wherein said first domain stabilizes over a time period to produce long-term level reflecting adequate microcirculatory delivery of glucose and oxygen to said sensor.

77. (Previously presented) The method of claim 34, wherein said first domain is formed from a material selected from the group consisting of polytetrafluoroethylene, hydrophilic polyvinylidene fluoride, mixed cellulose esters, polyvinyl chloride, polyethylene, Teflon, cellulose acetate, cellulose nitrate, polycarbonate, polyester, nylon, polypropylene, polymethacrylate, polysulfone, mixed esters of cellulose polyvinylidene difluoride, silicone, and polyacrylonitrile.

78. (Previously presented) The method of claim 34, wherein said first domain comprises a material that has a characteristic of stimulating growth of new vascular structures by said host close to said device.

79. (Previously presented) The method of claim 34, wherein said sensor senses glucose using an enzymatic mechanism.

Appl. No. : **09/447,227**
Filed : **November 22, 1999**

80. (Previously presented) The method of claim 34, wherein said sensor senses glucose using a non-enzymatic mechanism.

81. (Previously presented) The method of claim 34, wherein said sensor senses glucose using a resonance mechanism.

82. (Previously presented) The method of claim 34, wherein said sensor senses glucose using an acoustic wave mechanism.

83 (Previously presented) The method of claim 34, wherein said sensor senses glucose using an optical mechanism.

84-87. (Canceled)